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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,527	02/06/2001	Jennifer Hillman	PF-0576 USN	5045

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EXAMINER	
HUTSON, RICHARD G	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/762,527	HILLMAN ET AL.	
	Examiner	Art Unit	
	Richard G. Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1,2,7,8 and 15-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-6 and 9-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are still at issue and are present for examination.

Election/Restrictions

Applicant's election with traverse of Group II and Group A, drawn to SEQ ID NO: 3 or a sequence encoding SEQ ID NO: 1, Claims 3-6 and 9-14, in the paper of 7/19/2004, is acknowledged. The traversal is on the ground(s) that as per the MPEP, Section 803.04, the commissioner has decided to permit a reasonable number of nucleotide sequences to be claimed in a single application, and the office has "determined that normally ten sequences constitute a reasonable number for examination purposes". This argument has been considered in full and is found non-persuasive because as applicants point out, "up to ten independent and distinct sequences" may be examined in a single application, and the two chosen sequences (i.e. SEQ ID NO: 3 and 1) are encompassed by "up to ten". Further, applicants referred to sequences are each completely independent and distinct amino acid and nucleic acid sequences that have absolutely no relationship to each other beyond applicants disclosure of "extracellular adhesive proteins". This includes many different proteins and their encoding genes which have functions that are completely different, distinct and unrelated to each other. Thus a proper search and examination of more then the elected polynucleotide sequences would certainly create an undue burden on the office. Further, applicants claimed genus is not only drawn to each of these independent and distinct sequences, but also to fragments thereof.

Applicants further traverse the restriction requirement on the basis that the unity of invention standard must be applied in national stage applications as per MPEP, Section 1850. Applicants further submit Example 17, part 2 of Annex B in support of their position that the protein and DNA sequences should be kept together. This argument is acknowledged in full however found non-persuasive for the reasons previously stated, the unity of invention standard was applied to this national stage application in making the previous restriction requirement.

For applicants convenience, the basis of the restriction is herein repeated.

The inventions listed as Groups I through VIII and (A) through (B) do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups I through VIII share a technical relationship which corresponds to a polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1, 2 and fragments thereof. Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. The Sigma Catalog (1993) teaches a number of bioactive polypeptides including those comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1, 2 and fragments thereof, such as “Gly-Gly-Arg” and “Gly-Gln” (see page 1089 of the 1993 Sigma Catalog). A

fragment of SEQ ID NOs: 1 or 2 may be as small as a single amino acid such as alanine or glutamine. Thus, the shared technical feature of the groups is not a "special technical feature", unity of invention between the groups does not exist.

Thus the unity of invention standard has been applied, and the different groups do not share unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 2, 7, 8 and 15-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in the paper of 5/10/2004.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

No information disclosure statement is currently in file.

Claim Objections

Claims 3-6 and 9-14 are objected to because of the following informalities:

Claims 3-6 and 9-14 contain non-elected subject matter (i.e. SEQ ID NO: 2/4).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite in the recitation of "stringent conditions" as the specification does not define what conditions constitute "stringent". While page 9 of the specification describes some conditions which are intended to be stringent, there is nothing to suggest that other conditions would not also be included within the scope of this term and in the art what is considered stringent varies widely depending on the individual situation as well as the person making the determination. As such it is unclear how homologous to the sequence of a gene encoding SEQ ID NO:3, a sequence must be to be included within the scope of these claims.

Claims 6 and 11 are indefinite in that they recite "a polynucleotide complementary to" and it is unclear if it is applicants intent to claim "a polynucleotide **fully** complementary to ". For the purpose of advancing prosecution this is how this recitation is interpreted and it is suggested that applicants amend this to clearly reflect this information.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-6 and 9-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 3-6 and 9-14 are directed to all possible polynucleotides encoding a polypeptide consisting of SEQ ID NO: 1 and fragments thereof, and expression vectors and host cells comprising said polynucleotide. The specification, however, only provides the representative species of SEQ ID NO: 1, encompassed by these claims. There is no disclosure of any particular structure to function/activity relationship in the disclosed species.

The genus of polynucleotides that are claimed is a large variable genus with potentiality of encoding many functionally unrelated proteins. The specification also fails to describe additional representative species of these polynucleotides by any identifying characteristics or properties other than the structural characteristics recited in claim 1, for which no predictability of function is apparent. Given this lack of additional representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 3-6 and 9-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for those polynucleotides comprising SEQ ID NO: 3, does not reasonably provide enablement for those polynucleotides encoding a polypeptide comprising a fragment of SEQ ID NO: 3 or those having 70% sequence identity to a polynucleotide encoding a fragment of SEQ ID NO: 3 and expression vectors and host cells comprising said polynucleotide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 3-6 and 9-14 are so broad as to encompass any polynucleotide encoding a polypeptide comprising a fragment of SEQ ID NO: 3 or those having 70% sequence

identity to a polynucleotide encoding a fragment of SEQ ID NO: 3 and expression vectors and host cells comprising said polynucleotide.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the utility of the large number of polynucleotides broadly encompassed by the claims. It would require undue experimentation of the skilled artisan to make and use the claimed polynucleotides with an undefined function/activity. The specification is limited to teaching use of those polynucleotides which encode polypeptides capable of use as extracellular adhesion proteins, but provides no guidance with regard to other uses of the additional polynucleotides encompassed by the claimed genus. In view of the great breadth of the claims, amount of experimentation required to make the claimed polynucleotides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to make and use the full scope of the polynucleotides encompassed by this claim.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including all possible polynucleotides encoding a polypeptide comprising a fragment of SEQ ID NO: 3 or those having 70% sequence identity to a polynucleotide encoding a fragment of SEQ ID NO: 3 and expression

vectors and host cells comprising said polynucleotide. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those polypeptides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-6 and 9-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al. (WO 98/31799, See IDS).

Ni et al. teach a 133 amino acid polypeptide galectin 11 (clone HJACE54, page 18 line 33-page 19, line 5) and the encoding polynucleotide, and a host cell and expression vector comprising said polypeptide. This polypeptide is 100 % identical to amino acid residues 204 to 336 of instantly disclosed SEQ ID NO: 1. Ni et al. further teach compositions of a therapeutically effective amount of said polypeptide and a pharmaceutically acceptable carrier or excipient (page 30). Thus claims 3-6 and 9-14 are anticipated.

Claims 3-6 and 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Su et al. (Proc. Natl. Acad. Sci. USA Vol 93, pp 7252-7257, July 1996).

Su et al. teach the *in vitro* production of the 317 amino acid polypeptide PCTA-1, the encoding polynucleotide, and an expression vector and host cell comprising said polynucleotide. This polypeptide comprises many regions of local identity to amino acid residues 38 to 336 of instantly disclosed SEQ ID NO: 1. For example amino acids 63-70 of the protein taught by Ni et al. are identical to amino acids 93-100 of instantly disclosed SEQ ID NO: 1. Su et al. teach an isolated polypeptide comprising a biologically active fragment and an immunogenic fragment of SEQ ID NO: 1. Su et al. further teach compositions of said polypeptide and an excipient (protein translation buffer). Thus claims 3-6 and 9-14 are anticipated.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3-6 and 9-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,168,920. An obvious type double patenting rejection is appropriate where conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the claim is either abticipated by, or would have been obvious over, the reference claim(s). See, e.g.., *In re* Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re* Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re* Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-7 of U.S. Patent No. 6,168,920 drawn to a polynucleotide encoding a polypeptide comprising SEQ ID NO: 1 anticipates claims 3-6 and 9-14 of the instant application.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax

phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
9/29/2004